IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: GRUNDLER, Christoph; GRUNDLER, Markus; HEINE, Daniel

SERIAL NO.: 10/531,058 ART UNIT: 4177

FILED: January 17, 2006 EXAMINER: Stuart, C. W.

TITLE: DEVICE AND METHOD FOR TEMPERING AND HUMIDIFYING GAS, ESPECIALLY RESPIRATORY AIR

Amendment D: REMARKS

Upon entry of the present amendments, previous Claims 25 and 26 have been amended. Reconsideration of the rejections, in light of the foregoing amendments and present remarks, is respectfully requested. The present amendments have been entered for the purpose of further distinguishing the present invention from the prior art.

In the Office Action, it was indicated that Claims 25 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Dobitz patent in view of the Jackson patent. Claim 26 was also objected to because of the of a minor informality.

As an overview to the present reply, Applicant has revised previous independent Claim 25 herein. In particular, it is now indicated in revised independent Claim 25 that the gas flows in the humidification direction in "a direction opposite to a direction in which the fluid flows". The limitation of the "respiratory gas flow generator" has also been introduced into new independent Claim 25. Applicant respectfully contends that these limitations serve to distinguish the present invention from the prior art. In particular, support for the "opposite direction of flow" limitation in found in the original specification in paragraph [0083] as follows:

> While water is trickling from the annulus 7 via the huge surface downwards into the bottom chamber 11 of the humidifier 2

> it heats and wets the filling material 10. At the same time respiratory gas from reservoir 1 is flowing in the opposite direction through the filling 10. By doing so the respiratory gas is heated and humidified. In the end the nearly saturated gas is conducted via the collecting chamber 12 to the respiratory gas flow generator 3.

The position of the gas flow generator was recited in the original specification in paragraph [0060] as follows:

> Doing so allows to feed the gas flow generator being situated downstream of the humidification chamber with already humidified gas thus avoiding the need to place the humidifier between the gas flow generator and the patient. Hence there is neither a compressible volume nor a pressure gradient added between gas flow generator and patient which is highly desirable.

Further support is found in paragraph [0078] as follows:

> The embodiment shows how the respiratory gas is taken from a reservoir 1 (i.e. pressurized gas, or wall outlet). While passing the humidifier 2 the usually very dry pressurized gas is conducted to a respiratory gas flow generator 3. Within the respiratory gas flow generator 3 the gas is depressurized to the respiratory pressure level needed for ventilation or respiratory therapy which might be slightly above ambient air pressure. Then the respiratory gas is conducted to the patient 5, using active temperature controlled respiratory tubing 4 connected to the respiratory gas generator.

The main advantage of the present invention, as now claimed, is that the compressible volume of the breathing system leading from the respiratory gas flow generator to the patient is very low. This is described in paragraph [0079] of the original specification as follows:

> In this embodiment the compressible volume of the breathing system leading from the respiratory gas flow generator 3 to patient 5 is very low.

Furthermore, by placing the humidifier upstream of the gas flow generator, the gas flow generator is always provided with humidified gas. Even if the respiratory gas flow changes significantly

during a single respiratory cycle, the respiratory gas delivered by the respiratory gas flow generator is of constant quality.

In conventional systems, the gas flow generator is usually placed upstream of the humidification device. This has the disadvantage that the known humidifier devices add an extra compressible volume to the respiratory circuit. Furthermore, a humidification of respiratory gas usually results not only in a change of the humidity of the gas but also undesired changes of temperature. Therefore, in those cases where the gas flow varies during a respiratory cycle, the patient has been provided with a respiratory gas of changing temperature. In contrast, in the present invention, the temperature and humidity of a respiratory gas is constant even if there are significant changes in gas flow.

It is important to the present invention to be able to cause the respiratory gas to be delivered to the respiratory gas flow generator with constant temperature and constant humidity. This achieved by conducting heated fluid and gas in opposite directions through the humidification chamber. The humidification chamber is positioned upstream of the generator.

Applicant respectfully contends that these features, in the paragraphs described hereinabove, distinguish the present invention from the prior art combination. The prior art patents do not show the respiratory flow generator as placed downstream of the humidification chamber. The prior art patents are not able to achieve constant temperature and humidity of a highly variable gas flow. This is an important feature that is demanded by customers. The gas is only "prepared" following a demand. The air can only be conditioned after the gas flow generator. In the present invention, the air is correctly humidified and properly temperature-controlled upon delivery to the gas flow generator.

The prior art Jackson patent is clearly distinguishable from the present invention as claimed herein. In the Jackson patent, the humidifier is positioned between the gas flow generator and the patient. Accordingly, the Jackson patent describes a device that adds extra compressible volume directly in front of the patient so that the output of the gas flow generator is delayed in its delivery to the patient. The gas flow can also experience changes in pressure. Additionally, the Jackson patent does not disclose the element of moving the fluid and the respiratory gas through the humidification chamber in opposite directions. Accordingly, the humidified respiratory gas leaving the humidification chamber of the Jackson patent has an undefined temperature.

In the Dobitz patent, it is described that the respirator, i.e. the gas flow generator, is placed upstream of the humidification device. Once again, it adds a compressible volume to the respiratory circuit. Additionally, the Dobitz patent does not provide a filling material for the humidification chamber. In the Dobitz patent, there is a provided an interior passage for the inspirited air that is surrounded by a foil material. The inspiratory gas flows inside the passage 6a. There is no filling material. The foil material is pervious to water vapor. As such, the respiratory gas can take up the water vapor.

Importantly, the foil material of the Dobitz patent has the same disadvantages of fiber-type humidifiers. These problems were discussed in paragraphs [0021] and [0022] of the original specification as follows:

> Partially permeable hollow fibers (e.g. from PTFE) are bundled, and the gas to be heated and humidified is directed through their luminae. The outer surface of the fibers is in contact with the fluid needed for humidification. The disadvantage of that design is the fibers´ limited life-time and mechanical as well as thermal durability. Moreover, the fibers' unsuitably high thermal resistance unduly restricts the heat transfer needed to compensate for

> evaporation coldness. Thus especially with high gas flow the heating of the gas is insufficient, which in turn leads to insufficient gas humidification. From theory increasing the water's temperature might compensate for those limitations. In case of a heavily varying gas flow, however, even forced heating of the fibers will not lead to constant humidification due to technical limitations of controlling the instantaneous fibre temperature as fast as required.

The combination of the Dobitz patent and the Jackson patent would mean that the water provided with the Dobitz "filling" would be routed through a device according to the Jackson patent. However, in the Dobitz patent, the water reservoir is opened to the surroundings. Accordingly, bacteria can be introduced into the water system and can enter into the humidification chamber. As such, it can pass into the respiratory gas. As such, the combination of the Dobitz and Jackson patents would present a very undesirable consequence from the intended combination. Such a consequence would never occur with the teachings of the present invention.

Applicant has revised dependent Claim 26 so as to have a proper dependency from Claim 25.

Based upon the foregoing analysis, Applicant contends that independent Claim 25 is now in proper condition for allowance. Additionally, those claims which are dependent upon independent Claim 25 should also be in condition for allowance. Reconsideration of the rejections and allowance

of the claims at an early date is earnestly solicited. Since no new claims have been added above those originally paid for, no additional fee is required.

Respectfully submitted,

October 7, 2010
Date

/John S. Egbert/
John S. Egbert: Reg. No. 30,627
Attorney for Applicant
Egbert Law Offices PLLC
412 Main Street, 7th Floor
Houston, Texas 77002
(713)224-8080
(713)223-4873 fax

Customer No. 24106